CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Publisher of *Nutrition Action Healthletter*

2710 '00 MAR -6 A9:38

February 10, 2000

Dr. Stephen Sundlof
Director, Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

We (and the other nonprofit groups) appreciated the opportunity to meet with you and Commissioner Jane Henney on January 6 to discuss FDA's activities on antibiotics used in agriculture. You expressed interest in how we would prioritize the antibiotics that we petitioned the FDA to ban for subtherapeutic use in livestock feed (Docket No. 99P-0485). We hope that this reply will enable you to give swifter attention to the drugs named in that petition filed on March 9, 1999.

The petition calls for the FDA to rescind the approvals for subtherapeutic use in livestock feed of seven antibiotics that are used in (or related to those used in) human medicine. While all of those approvals should be revoked, some are more hazardous to human health, and thus, should be addressed immediately.

Top priority should be given to virginiamycin, which is related to Synercid. Synercid, which only has been approved recently for use in people, may be the drug of last resort for treating severe, antibiotic-resistant, hospital-acquired infections. The use of virginiamycin in livestock can cause bacteria to become resistant to Synercid. Although Synercid had not been approved for use in people until the end of 1999, one to two percent of samples taken from people reveal colonization with Synercid-resistant bacteria. That resistance may cause treatment failure if those people become ill and need treatment with Synercid.

Erythromycin should be given the next highest priority by the FDA. Because of their ability to select for erythromycin resistance, lincomycin and tylosin should be considered with erythromycin. Erythromycin is used to treat *Campylobacter* infections in children (for whom fluoroquinolones are not approved) and fluoroquinolone-resistant *Campylobacter* infections in adults. Erythromycin is likely to become even more important because fluoroquinolone resistance rates among *Campylobacter* isolates are rising. The Centers for Disease Control and Prevention (CDC) estimates that twenty-one percent of human cases of *Campylobacter* are fluoroquinolone resistant. At that level of resistance, and as resistance increases, many physicians may stop using fluoroquinolones as the first line of defense for treating enteric

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Executive Director: *Michael Jacobson, Ph.D.*

infections and, instead, rely on erythromycin. Erythromycin also is used to treat infections in people who are allergic to penicillin and is good for treating certain types of pneumonia.

It is difficult to rank the relative importance of penicillin and tetracycline. In addition to being somewhat useful antibiotics for treating infections in people, the use of penicillin and tetracycline in people or livestock can select for bacteria that are multidrug resistant. Multidrug resistant bacteria are more difficult to treat. Data, if it were available on how much of each drug was used in livestock feed might be helpful for prioritizing. For example, if tetracycline were used ten times as often as penicillin in livestock feed, we would recommend prioritizing it higher than penicillin.

Penicillin is used to treat a wide range of infections such as ear, sinus, bladder, gonorrhea, oral infections, skin infections, strep throat, and bronchitis. For most people (those who aren't allergic) penicillin is a very useful drug for treating bacterial infections that are sensitive to it. Although many of the bacteria that penicillin works against are not foodborne, penicillin resistance may be transferred from foodborne pathogens (and gut commensal bacteria) to respiratory pathogens. Tetracycline is useful against some gram negative bacteria, such as *Salmonella.*

Bacitracin is the antibiotic of lowest priority in the CSPI petition. Bacitracin is only used topically and is not vital for treating serious human infections.

In conclusion, we urge you to take swift action to ban the subtherapeutic use in livestock feed of antibiotics important in human medicine. Such action would go a long way to protect the public health.

Sincerely,

Patricia Lieberman, Ph.D.
Staff Scientist

Michael F. Jacobson, Ph.D.
Executive Director

cc: Jane Henney, M.D., Commissioner, Food and Drug Administration
Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA

Mitchell, Bert

From: [redacted]
Sent: Friday, February 25, 2000 4:56 PM
To: Butler, Jennie C
Cc: [redacted]
Subject: 2/10/00 letter to CVM from CSPI. Subject - request to rescind subtherapeutic uses of antibiotics

I'm going to send you a letter of 2/10/00 from CSPI. Please add it to Docket No. 99P-0485.

I'll put a copy of this message on the front of it.